IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INGENUS PHARMACEUTICALS, LLC, Plaintiff, v. HETERO USA, INC., HETERO LABS LTD., and HETERO LABS LTD. UNIT-VI, Defendants.	C.A. No. 1:24-cv-01025-JLH

DEFENDANTS' HETERO USA, INC., HETERO LABS LTD., AND HETERO LABS LTD. UNIT-VI'S UNOPPOSED MOTION FOR LEAVE TO FILE FIRST AMENDED AFFIRMATIVE DEFENSES

Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI (collectively, "Hetero" or "Defendants"), by their undersigned attorneys, hereby request leave to file the First Amended Affirmative Defenses, as provided by Rule 15 of the Federal Rules of Civil Procedure. A copy of the Answer to the Complaint, First Amended Affirmative Defenses, and Counterclaims is attached as Exhibit A. A copy of a redline that tracks the changes to the Amended Affirmative Defenses is attached as Exhibit B. Plaintiff Ingenus Pharmaceuticals, LLC ("Ingenus") does not oppose this request.

I. NATURE OF THE ACTION AND STAGE OF THE PROCEEDINGS

Ingenus sued Hetero on September 11, 2024, asserting claims of patent infringement of U.S. Patent No. 10,993,952 ("the '952 Patent"). On May 9, 2025, the Northern District of Illinois court held the '952 patent indefinite and, therefore, invalid. Based upon this finding, Hetero seeks leave to amend its affirmative defenses to assert the defense of collateral estoppel. Ingenus does not oppose the filing of the First Amended Affirmative Defenses.

II. ARGUMENT

A party may amend a pleading with the opposing party's written consent or leave of court. Fed. R. Civ. P. 15(a). Leave to amend a pleading prior to trial is to be given freely when justice requires. Fed. R. Civ. P. 15(a)(2). In this case, Hetero seeks to amend its affirmative defenses to add an affirmative defense that arose because of a recent decision in the Northern District of Illinois that found the '952 patent invalid. Ingenus does not oppose the motion. Thus, pursuant to Federal Rule of Civil Procedure 15(a), this motion should be granted.

III. CONCLUSION

For the foregoing reasons, Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI respectfully request that the Court grant the unopposed motion for leave to file the proposed First Amended Affirmative Defenses.

Dated: June 24, 2025

/s/ Kenneth L. Dorsney
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SO ORDERED this ____ day of _____, 2025.

_____
UNITED STATES DISTRICT JUDGE

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INGENUS PHARMACEUTICALS, LLC, Plaintiff, v. HETERO USA, INC., HETERO LABS LTD., and HETERO LABS LTD. UNIT-VI, Defendants.	C.A. No. 1:24-cv-01025-JLH

DEFENDANTS' HETERO USA, INC., HETERO LABS LTD., AND HETERO LABS LTD. UNIT-VI'S ANSWER TO THE COMPLAINT, FIRST AMENDED AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI (collectively, "Hetero" or "Defendants"), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement filed by Plaintiff Ingenus Pharmaceuticals, LLC ("Plaintiff"), state as follows. Pursuant to Fed R. Civ. P. 8(b)(3), Hetero denies all allegations in Plaintiff's Complaint except those expressly admitted below.

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, arising from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 219271 to the United States Food and Drug Administration ("FDA). Defendants' ANDA seeks FDA approval to market and sell Cyclophosphamide Solution; 500mg/2.5ml (200mg/ml), lgm/5ml (200mg/ml), and 2gm/10ml (200mg/ml) ("Defendants' ANDA Products") prior to the expiration of U.S. Patent No. 10,993,952 ("the '952 Patent" or "the patent in suit"). A true and correct copy of the '952 Patent is attached hereto as Exhibit A.

ANSWER: Paragraph 1 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that Plaintiff's Complaint purports to assert an action for patent infringement based on Hetero's filing of an Abbreviated New Drug Application ("ANDA") seeking approval from the U.S. Food and Drug Administration ("FDA") to commercially market generic versions of Cyclophosphamide Solution prior to the expiration of U.S. Patent No. 10,993,952 ("the '952 Patent" or the "Patent-in-Suit"). Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 1 of the Complaint and therefore denies them.

THE PARTIES

2. Ingenus Pharmaceuticals, LLC ("Ingenus") is a corporation organized and existing under the laws of the state of Florida having its principal place of business at 4190 Millenia Blvd., Orlando, Florida 32839.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 2 of the Complaint and, therefore, denies all allegations.

3. On information and belief, Defendant Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

ANSWER: Admitted.

4. On information and belief, Hetero Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telangana, India.

ANSWER: Denied.

5. On information and belief, Defendant Hetero Labs Ltd. Unit-VI is a division of Hetero Labs Ltd. and its principal place of business is located at Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India.

ANSWER: Denied.

6. On information and belief, Hetero Labs Ltd. is a parent company of Hetero USA Inc.

ANSWER: Admitted.

7. On information and belief, Hetero Labs Ltd., Hetero Labs Ltd. Unit-VI, and Hetero USA Inc. are related entities and each entity undertakes certain activities related to the development, manufacture, marketing, and/or sale of drug products in the United States and in this Judicial District.

ANSWER: Denied.

8. Upon information and belief, Defendants derive substantial revenue from the sale of generic pharmaceutical products in the United States and Delaware.

ANSWER: Denied.

JURISDICTION AND VENUE

9. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 1 *et seq.*, and alleges infringement of the ’952 Patent.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that Plaintiff’s Complaint purports to assert an action for patent infringement under the patent laws of the United States, including 35 U.S.C. § 1 *et seq.*, and alleges infringement of the ’952 Patent. Hetero denies any remaining allegations contained in Paragraph 9 of the Complaint.

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has subject matter jurisdiction over this action. Hetero denies any remaining allegations contained in Paragraph 10 of the Complaint.

11. This Court has personal jurisdiction over Hetero USA Inc. On information and belief, Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Hetero USA Inc. maintains an agent for service of process at 3500 S Dupont Highway, Dover DE 19901.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero USA Inc. Hetero denies any remaining allegations contained in Paragraph 11 of the Complaint.

12. This Court has personal jurisdiction over Hetero USA Inc. at least because, upon information and belief, Hetero USA Inc. has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Hetero USA Inc. directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Hetero USA Inc. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or

things used or consumed in Delaware, thereby demonstrating that Hetero USA Inc. has continuous and systematic contacts with Delaware.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero USA Inc. Hetero denies any remaining allegations contained in Paragraph 12 of the Complaint.

13. Hetero USA Inc. regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g, , Novartis Pharmaceuticals Corp. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 19-2053-LPS (D. Del. Jan. 27, 2020), D.I. 30; *Genentech, Inc. et al. v. Hetero Labs Ltd. et al.*, C.A. No. 19-178-RGA (D. Del. Apr. 1, 2019), D.I. 11; *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, C.A. No. 17- 825-MN (D. Del. Oct. 16, 2017), D.I. 13; *Sanofi-Aventis U.S. LLC, et al. v. Actavis LLC, et al.*, C.A. No. 20-804-RGA (D. Del. July 20, 2020), D.I. 36; *Bristol-Myers Squibb Co. et al. v. Hetero USA Inc. et al.*, C.A. No. 17-376-LPS (D. Del. Jun. 16, 2017), D.I. 9; and *Amgen Inc. v. Hetero USA Inc. et al.*, C.A. No. 16-928-GMS (D. Del. Dec. 2, 2016), D.I. 12.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero USA Inc. Hetero denies any remaining allegations contained in Paragraph 13 of the Complaint.

14. This Court has personal jurisdiction over Hetero Labs Ltd. at least because, upon information and belief, Hetero Labs Ltd. has purposefully availed itself of the benefits and

protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Hetero Labs Ltd. directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Hetero Labs Ltd. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, thereby demonstrating that Hetero Labs Ltd. has continuous and systematic contacts with Delaware.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero Labs Ltd. Hetero denies any remaining allegations contained in Paragraph 14 of the Complaint.

15. Hetero Labs Ltd. regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g,* [sic] *Novartis Pharmaceuticals Corp. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 19-2053-LPS (D. Del. Jan. 27, 2020), D.I. 30; *Genentech, Inc. et al. v. Hetero Labs Ltd. et al.*, C.A. No. 19-178-RGA (D. Del. Apr. 1, 2019), D.I. 11; *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, C.A. No. 17- 825-MN (D. Del. Oct. 16, 2017), D.I. 13; *Sanofi-Aventis U.S. LLC, et al. v. Actavis LLC, et al.*, C.A. No. 20-804-RGA (D. Del. July 20, 2020), D.I. 36; *Bristol-Myers Squibb Co. et al. v. Hetero USA Inc. et al.*, C.A. No. 17-376-LPS (D. Del. Jun. 16, 2017), D.I. 9; and *Amgen Inc. v. Hetero USA Inc. et al.*, C.A. No. 16-928-GMS (D. Del. Dec. 2, 2016), D.I. 12.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero Labs Ltd. Hetero denies any remaining allegations contained in Paragraph 15 of the Complaint.

16. Hetero Labs Ltd. is also subject to personal jurisdiction in the State of Delaware because Hetero Labs Ltd. has committed, aided, abetted, contributed to, and/or participated in the commission of tortious acts of patent infringement under 35 U.S.C. § 271(e)(2) that have led and/or will lead to foreseeable harm and injury to Plaintiff Ingenus Pharmaceuticals LLC.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero Labs Ltd. Hetero denies any remaining allegations contained in Paragraph 16 of the Complaint.

17. This Court has personal jurisdiction over Hetero Labs Ltd. Unit-VI, at least because, upon information and belief, Hetero Labs Ltd. Unit-VI has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Hetero Labs Ltd. Unit-VI directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Hetero Labs Ltd. Unit-VI regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, thereby demonstrating that Hetero Labs Ltd. Unit-VI has continuous and systematic contacts with Delaware.

ANSWER: Denied.

18. Hetero Labs Ltd. Unit-VI regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Novartis Pharmaceuticals Corp. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 19-2053-LPS (D. Del. Jan. 27, 2020), D.I. 30; *Genentech, Inc. et al. v. Hetero Labs Ltd. et al.*, C.A. No. 19-178-RGA (D. Del. Apr. 1, 2019), D.I. 11; *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, C.A. No. 17- 825-MN (D. Del. Oct. 16, 2017), D.I. 13; *Sanofi-Aventis U.S. LLC, et al. v. Actavis LLC, et al.*, C.A. No. 20-804-RGA (D. Del. July 20, 2020), D.I. 36; *Bristol-Myers Squibb Co. et al. v. Hetero USA Inc. et al.*, C.A. No. 17-376-LPS (D. Del. Jun. 16, 2017), D.I. 9; and *Amgen Inc. v. Hetero USA Inc. et al.*, C.A. No. 16-928-GMS (D. Del. Dec. 2, 2016), D.I. 12.

ANSWER: Denied.

19. Hetero Labs Ltd. Unit-VI is also subject to personal jurisdiction in the State of Delaware because Hetero Labs Ltd. Unit-VI has committed, aided, abetted, contributed to, and/or participated in the commission of tortious acts of patent infringement under 35 U.S.C. § 271(e)(2) that have led and/or will lead to foreseeable harm and injury to Plaintiff Ingenus Pharmaceuticals LLC.

ANSWER: Denied.

20. This Court has personal jurisdiction over Hetero at least because, upon information and belief, Hetero is the current owner of Abbreviated New Drug Application (ANDA) No. 219271 ("Hetero's ANDA") and is seeking final approval of that ANDA to engage in the commercial use, sale, and/or distribution of cyclophosphamide solution for intravenous injection, 500 mg/2.5 mL (200 mg/mL), 1 gm/5 mL (200 mg/mL), and 2 gm/10 mL (200 mg/mL) ("Hetero's

ANDA Product" or "ANDA Product"), throughout the United States, including in Delaware, before the expiration of the '952 Patent.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero USA Inc. and Hetero Labs Ltd. Hetero denies any remaining allegations contained in Paragraph 20 of the Complaint.

21. This Court has personal jurisdiction over Hetero at least because, upon information and belief, if Hetero's ANDA receives final approval, Hetero's ANDA Product will be manufactured, sold, distributed, and/or used by Hetero in Delaware; prescribed by physicians practicing in Delaware; and/or administered to patients in Delaware.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero USA Inc. and Hetero Labs Ltd. Hetero denies any remaining allegations contained in Paragraph 21 of the Complaint.

22. Hetero committed an act of infringement of the '952 Patent by submitting and maintaining ANDA No. 219271 with the intent to make, use, offer to sell, and/or sell the drug products that are the subject of ANDA No. 219271 in this Judicial District, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Plaintiff, which manufactures Cyclophosphamide Injection for sale and use throughout the United States, including within this judicial district. On information and belief and as indicated by a letter dated July 31, 2024, sent by Hetero USA, Inc. and addressed to Ingenus Pharmaceuticals LLC, Leiutis Pharmaceuticals LLP and Dr. Reddy's laboratories, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (hereinafter, the "Notice

Letter"), ANDA No. 219271 was prepared and filed with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

ANSWER: Denied.

23. On information and belief, Hetero plans to sell its ANDA Product in the State of Delaware, list the ANDA Product on the State of Delaware' prescription drug formulary, and seek Medicaid reimbursements for sales of the ANDA Product in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Denied.

24. On information and belief, Hetero intends that its proposed ANDA Product will be distributed and sold in Delaware and will thereby displace sales of Plaintiff's Cyclophosphamide Injection, causing injury to Ingenus. Hetero intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed ANDA Product.

ANSWER: Denied.

25. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest the propriety of venue in this District. Hetero denies all remaining allegations of Paragraph 25.

PLAINTIFF'S APPROVED DRUG PRODUCT AND U.S. PATENT No. 10,993,952

26. By License Agreement of June 11, 2024, Dr. Reddy's Laboratories, Inc. ("DRL") has become Ingenus' Licensee of New Drug Application (NDA) No. 212501, which was approved by the Food and Drug Administration ("FDA") for the sale and manufacture of Cyclophosphamide

solution for intravenous use ("NDA Product"). The active ingredient in the Cyclophosphamide NDA Product is cyclophosphamide. The FDA approved NDA No. 212501 on July 30, 2020.

ANSWER: Hetero admits that NDA No. 212501 was approved by the Food and Drug Administration ("FDA") for the sale and manufacture of Cyclophosphamide solution. Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 26 of the Complaint and, therefore, denies them.

27. Under the terms of the License Agreement, Ingenus manufactures and supplies to DRL the Products approved under NDA 212501 and DRL markets and commercializes the same, subject to the terms of the License Agreement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 27 of the Complaint and, therefore, denies all allegations.

28. NDA No. 212501 is directed to Cyclophosphamide 200 mg/mL (500 mg/ 2.5 mL and 1 g/ 5 mL) in a multiple-dose vial. A supplemental dosage form 200 mg/mL (2 g/ 10 ml) was approved November 19, 2021, under New Drug Application No. N212501.

ANSWER: Hetero admits that NDA No. 212501 is directed to Cyclophosphamide 200 mg/mL (500 mg/ 2.5 mL and 1 g/ 5 mL). Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 28 of the Complaint and, therefore, denies them.

29. Plaintiff's Cyclophosphamide NDA Product is an injectable solution indicated for the treatment of malignant diseases such as malignant lymphomas (Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma); multiple myeloma, leukemias (chronic lymphocytic leukemia, chronic granulocytic leukemia,

acute myelogenous and monocytic leukemia, acute lymphoblastic (stem-cell) leukemia); mycosis fungoides, neuroblastoma, adenocarcinoma of the ovary, retinoblastoma, and breast carcinoma.

ANSWER: Hetero admits that the prescribing information for Plaintiff's Cyclophosphamide product speaks for itself. Hetero denies the remaining allegations of Paragraph 29 of the Complaint.

30. Plaintiff's Cyclophosphamide NDA Product's recommended dosage is 40 mg per kg to 50 mg per kg in divided doses over 2 to 5 days.

ANSWER: Hetero admits that the prescribing information for Plaintiff's Cyclophosphamide product speaks for itself. Hetero denies the remaining allegations of Paragraph 30 of the Complaint.

31. The '952 Patent, entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations," was duly and legally issued by the U.S. Patent and Trademark Office on May 4, 2021.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '952 patent is entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations." Hetero denies that the '952 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph31.

32. Ingenus is the sole owner and assignee of the '952 Patent, based on an Assignment of all right, title and interest by Assignor Leiutis Pharmaceuticals LLP of July 4, 2024, recorded at the U.S. Patent and Trademark Office on July 10, 2024 at Reel/Frame No. 067935/0049. Prior to the Assignment by Leiutis, Ingenus and Leiutis were co-assignees of the '952 Patent.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero is without sufficient information with which to form a

belief as to the truth or accuracy of the allegations in Paragraph 32 of the Complaint and, therefore, denies all allegations.

33. Pursuant to 21 U.S.C. § 355(b)(1), the '952 Patent was submitted to FDA with NDA No. 212501 and was subsequently listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for Cyclophosphamide Injection.

ANSWER: Upon information and belief, Hetero admits that FDA's Orange Book lists the '952 patent in connection with NDA No. 212501. Hetero lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 33 and, therefore, denies those allegations.

DEFENDANTS' ANDA NO. 219271

34. On information and belief, Defendants have submitted ANDA No. 219271 to FDA, or caused ANDA No. 219271 to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of cyclophosphamide injection as purported generic versions of Plaintiff's NDA Products prior to the expiration of the '952 Patent.

ANSWER: Hetero admits that it submitted ANDA No. 219721 seeking approval to market Hetero's Proposed ANDA Product. Hetero denies all remaining allegations of Paragraph 34 of the Complaint.

35. On information and belief, Hetero USA Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI acted collaboratively in the preparation and submission of ANDA No. 219271 and Hetero's Proposed ANDA Product, and all intend to directly benefit from and have a financial stake in the approval of the ANDA.

ANSWER: Denied.

36. On information and belief, following any FDA approval of ANDA No. 219271, Hetero USA Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI will work in concert with one another to make, use, offer to sell, and/or sell the drug product that is the subject of ANDA No. 219271 throughout the United States, and/or import such drug product into the United States, including in this Judicial District.

ANSWER: Denied.

37. On information and belief, FDA has not approved Defendants' ANDA.

ANSWER: Admitted.

38. By letter dated July 31, 2024, Hetero USA, Inc. notified Ingenus Pharmaceuticals LLC, Leiutis Pharmaceuticals LLP and Dr. Reddy's Laboratories, Inc. that Hetero submitted to FDA ANDA No. 219271 containing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '952 Patent, which is listed in the Orange Book for Plaintiff's NDA Products, asserting that the'952 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Hetero's Proposed ANDA Product. Plaintiff reserves all rights to challenge the sufficiency of Defendants' ANDA and Notice Letter.

ANSWER: Hetero admits that it sent written notice of a Paragraph IV Certification ("Hetero's Notice Letter") to Plaintiffs on or around July 31, 2024. Hetero's Notice Letter speaks for itself. Hetero denies all remaining allegations of Paragraph 38 of the Complaint.

39. On information and belief, Defendants seek approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Product before expiration of the '952 Patent. Hence, Defendants' purpose in submitting ANDA No. 219271 with a Paragraph

IV certification is to market the ANDA product described therein before the expiration of the '952 Patent.

ANSWER: Hetero's Notice Letter speaks for itself. Hetero denies all remaining allegations of Paragraph 39 of the Complaint.

40. On information and belief, if approved, the ANDA Product will have the same indication as Plaintiff's Cyclophosphamide NDA Product. On further information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 219271 for the ANDA Product is the treatment of malignant diseases as described in Plaintiff's NDA.

ANSWER: Hetero's proposed labeling speaks for itself. Hetero denies all remaining allegations in Paragraph 40 of the Complaint.

41. On information and belief, if FDA approves Defendants' ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Product, within the United States, including within the State of Delaware, or will import the ANDA Product into the United States, including into the State of Delaware.

ANSWER: Denied.

42. On information and belief, if FDA approves Defendants' ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product in a manner that infringes the '952 Patent.

ANSWER: Denied.

43. This action is being brought within forty-five days of Plaintiff's receipt of the Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). Accordingly, Plaintiff is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that this action is being brought within 45 days of Hetero's Notice Letter. Hetero denies all remaining allegations of Paragraph 43 of the Complaint.

FIRST COUNT
(Hetero's Infringement of the '952 Patent)

44. Plaintiff repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

45. Upon information and belief, Hetero submitted or caused the submission of ANDA No. 219271 to FDA, seeking FDA approval of Defendants' ANDA.

ANSWER: Admitted.

46. Plaintiff owns substantial rights, title, and interest in and to the '952 Patent.

ANSWER: Denied.

47. Hetero's ANDA Product falls within one or more claims of the '952 Patent.

ANSWER: Denied.

48. Hetero does not contest infringement of any claims of the '952 Patent in its Notice Letter. If Hetero had a factual or legal basis to contest infringement of any claims of the '952 Patent, Hetero was required by applicable regulations to state such a basis in its Notice Letter. See 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

ANSWER: Denied.

49. Under 35 U.S.C. § 271(e)(2)(A), Hetero's submission of Hetero's ANDA with a Paragraph IV certification to the '952 Patent for the purpose of obtaining approval to engage in

the commercial manufacture, use, or sale of Hetero's ANDA Product before the expiration of the '952 Patent is itself an act of infringement of the '952 Patent.

ANSWER: Denied.

50. If approved by the FDA, the importation, manufacture, sale, offer for sale, or use of the ANDA Product within the United States will infringe, either literally or under the doctrine of equivalents, one or more claims of the '952 Patent under 35 U.S.C. § 271(a).

ANSWER: Denied.

51. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '952 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendants' ANDA, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby induce infringement of one or more claims of the '952 Patent. On information and belief, upon FDA approval, Defendants will intentionally encourage acts of direct infringement with knowledge of the '952 Patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

52. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the '952 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants' ANDA, Defendant will offer to sell or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of one or more claims of the '952 Patent. On information and belief, Defendants have had and continues to have knowledge of the '952 Patent and knowledge that its acts will lead to infringement of the patent. On information and belief, Defendants have had and continue to have

knowledge that the ANDA Product is especially made or especially adapted for a use that infringes the ’952 Patent and that there are no substantial noninfringing uses for the ANDA Product.

ANSWER: Denied.

53. Defendants had actual and constructive notice of the ’952 Patent prior to filing Defendants’ ANDA, and was aware that the filing of Defendants’ ANDA with the request for FDA approval prior to the expiration of the ’952 Patent would constitute an act of infringement of the ’952 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not infringe, contribute to the infringement of, and/or induce the infringement of the ’952 Patent.

ANSWER: Denied.

54. Defendants filed their ANDA without adequate justification for asserting the ’952 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants’ conduct in certifying invalidity, unenforceability, and/or noninfringement with respect to the ’952 Patent was willful and renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285 and entitles Plaintiff to recovery of their attorneys’ fees and such other relief as this Court deems proper.

ANSWER: Denied.

55. Plaintiff will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the ’952 Patent. Plaintiff does not have an adequate remedy at law and considering the balance of hardships between Plaintiff and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

GENERAL DENIAL AND RESPONSE TO PRAYER FOR RELIEF

To the extent not specifically admitted above, Hetero hereby denies all allegations in the Complaint. Hetero further denies that Plaintiff is entitled to any relief whatsoever. Hetero denies that Plaintiff is entitled to the judgment or other relief prayed for in Paragraphs A-J of the Complaint under the heading PRAYER FOR RELIEF.

HETERO'S DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Hetero avers and asserts the following separate defenses to the Complaint:

FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '952 PATENT)

The claims of the '952 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '952 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219271 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '952 Patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '952 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219271 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '952 Patent.

FOURTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiff's Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

FIFTH SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

Plaintiff's Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and/or (c).

SIXTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM FOR EXCEPTIONAL OR WILLFUL INFRINGEMENT)

Plaintiff fails to state a proper claim for an exceptional case and/or willful infringement.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to injunctive relief against Hetero because Plaintiff's alleged damages are not immediate or irreparable, and therefore Plaintiff has an adequate remedy at law. Moreover, considering the balance of hardships between the parties, and the public interest in fostering the prompt introduction of generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to attorney's fees against Hetero because Plaintiff has not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285.

NINTH AFFIRMATIVE DEFENSE

35 U.S.C. § 288 prevents Plaintiff from recovering any costs associated with this action.

TENTH AFFIRMATIVE DEFENSE

Plaintiff's allegations are barred, in whole or in part, by the doctrines of waiver, estoppel and/or prosecution history estoppel.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's allegations are barred by the doctrine of collateral estoppel based on the judgment in *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case No. 22-02868.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Hetero reserves the right to plead additional separate defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

HETERO'S COUNTERCLAIMS

For its counterclaims against Counterclaim-Defendant Ingenus Pharmaceuticals, LLC ("Ingenus" or "Counterclaim-Defendant"), Counterclaim-Plaintiff Hetero USA, Inc., Hetero Labs Ltd. Unit-V, and Hetero Labs Ltd. (collectively, "Hetero" or "Counterclaim-Plaintiffs"), state as follows:

PARTIES

1. On information and belief, Ingenus is a corporation organized and existing under the laws of the state of Florida having its principal place of business at 4190 Millenia Blvd., Orlando, Florida 32839.

2. Counterclaim-Plaintiff Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at Floor 9-11, Tower 30, RMZ Nexity Sy. No. 83/1, Knowledge City, Raidurg, Hyderabad – 500081, Telangana, India.

3. Counterclaim-Plaintiff Hetero USA, Inc. is a corporation organized and existing

under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

NATURE OF THE ACTION

4. Hetero seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that United States Patent No. 10,993,952 ("the '952 patent" or the "Patent-In-Suit") is invalid and/or not infringed.

JURISDICTION AND VENUE

5. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Ingenus because, among other reasons, Ingenus subjected itself to the jurisdiction of this Court by filing its complaint here.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Plaintiff's choice of forum.

8. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the Patent-in-Suit.

BACKGROUND

A. FDA Approval of New Brand Name Drugs

9. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

10. Under the FFDCA, an applicant seeking to market a new brand-name drug must

prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

11. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

12. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

13. FDA's duties with respect to the Orange Book are purely ministerial. If the NDA holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval of New Generic Drugs

14. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

15. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

16. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

17. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

18. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of each of its paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

19. Upon receiving notice of the paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

20. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the paragraph IV certifications because doing so, regardless of merit, prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions requiring court actions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

21. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the proposed product in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

C. Hetero's ANDA and Plaintiff' Complaint

22. Hetero submitted Abbreviated New Drug Application ("ANDA") No. 219271 ("Hetero's ANDA") to obtain FDA approval to engage in the commercial manufacture, use, and sale of generic Cyclophosphamide Solution ("Hetero's ANDA Product").

23. On information and belief, Ingenus holds approved New Drug Application ("NDA") No. 212501 for Cyclophosphamide Solution under Section 505(b) of the Federal Food Drug and Cosmetic Act ("FFDCA").

24. Hetero's ANDA shows that Hetero's ANDA Products are bioequivalent to the products that are the subject of NDA No. 212501.

25. On information and belief, Ingenus caused the '952 patent to be listed in the publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly called the "Orange Book," as a patent that purportedly claims the drug listed in, and/or purportedly claim a method of using the drug for which Ingenus submitted, NDA No. 212501.

26. The '952 patent is entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations" and the issue date identified on the cover of the '952 patent is May 4, 2021.

27. Hetero's ANDA contains "Paragraph IV" certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '952 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Hetero's ANDA Product.

28. On July 31, 2024, Hetero sent Plaintiff written notice of Hetero's Paragraph IV Certifications ("Hetero's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Hetero's Notice Letter asserted that the claims of the '952 patent are invalid, unenforceable, and/or will not be infringed by Hetero's ANDA or the products or activities described therein.

29. Hetero's Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV certifications included in Hetero's ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

30. On September 11, 2024, Plaintiff filed the present lawsuit alleging infringement of the '952 patent. There has been and now is an actual and justiciable controversy between Hetero and Plaintiff as to whether Hetero's ANDA Product infringes, induces infringement, or contributes to the infringement of any valid and enforceable claim of the '952 patent.

COUNT I
Declaratory Judgment of Non-Infringement of the '952 Patent

31. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

32. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '952 patent.

33. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '952 patent is not infringed by Hetero's ANDA or the products or activities described therein.

34. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '952 patent and is not liable for such infringement.

COUNT II
Declaratory Judgment of Invalidity of the '952 Patent

35. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

36. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the '952 patent are invalid.

37. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '952 patent are invalid.

38. Hetero is entitled to a declaration that all claims of the '952 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

HETERO'S REQUEST FOR RELIEF

WHEREFORE, Hetero respectfully requests that this Court enter a judgment in its favor and against Plaintiff as follows:

(a) Dismissing the Complaint with prejudice and entering judgment for Hetero;

(b) Declaring that no valid claim of the Patent-in-Suit would be infringed by the manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Products pursuant to ANDA No. 219271

(c) Declaring that the claims of the Patent-in-Suit are invalid;

(d) Entering judgment for Hetero on its affirmative defenses and any and all additional defenses and counterclaims that discovery may reveal;

(e) Enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Counterclaim-Defendant from threatening to assert or otherwise attempting to enforce the Patent-in-Suit against Hetero, its customers, suppliers, or anyone in privity with Hetero;

(f) Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Hetero its reasonable attorneys' fees and costs incurred in this action;

(g) Awarding Hetero its costs and expenses incurred in this action; and

(h) Awarding Hetero such other and further relief as this Court may deem proper.

Dated: June ___, 2025

/s/ Kenneth L. Dorsney

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Attorneys for Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INGENUS PHARMACEUTICALS, LLC, Plaintiff, v. HETERO USA, INC., HETERO LABS LTD., and HETERO LABS LTD. UNIT-VI, Defendants.	C.A. No. 1:24-cv-01025-JLH

DEFENDANTS' HETERO USA, INC., HETERO LABS LTD., AND HETERO LABS LTD. UNIT-VI'S ANSWER TO THE COMPLAINT, FIRST AMENDED AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI (collectively, "Hetero" or "Defendants"), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement filed by Plaintiff Ingenus Pharmaceuticals, LLC ("Plaintiff"), state as follows. Pursuant to Fed R. Civ. P. 8(b)(3), Hetero denies all allegations in Plaintiff's Complaint except those expressly admitted below.

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, arising from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 219271 to the United States Food and Drug Administration ("FDA). Defendants' ANDA seeks FDA approval to market and sell Cyclophosphamide Solution; 500mg/2.5ml (200mg/ml), lgm/5ml (200mg/ml), and 2gm/10ml (200mg/ml) ("Defendants' ANDA Products") prior to the expiration of U.S. Patent No. 10,993,952 ("the '952 Patent" or "the patent in suit"). A true and correct copy of the '952 Patent is attached hereto as Exhibit A.

ANSWER: Paragraph 1 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that Plaintiff's Complaint purports to assert an action for patent infringement based on Hetero's filing of an Abbreviated New Drug Application ("ANDA") seeking approval from the U.S. Food and Drug Administration ("FDA") to commercially market generic versions of Cyclophosphamide Solution prior to the expiration of U.S. Patent No. 10,993,952 ("the '952 Patent" or the "Patent-in-Suit"). Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 1 of the Complaint and therefore denies them.

THE PARTIES

2. Ingenus Pharmaceuticals, LLC ("Ingenus") is a corporation organized and existing under the laws of the state of Florida having its principal place of business at 4190 Millenia Blvd., Orlando, Florida 32839.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 2 of the Complaint and, therefore, denies all allegations.

3. On information and belief, Defendant Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

ANSWER: Admitted.

4. On information and belief, Hetero Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telangana, India.

ANSWER: Denied.

5. On information and belief, Defendant Hetero Labs Ltd. Unit-VI is a division of Hetero Labs Ltd. and its principal place of business is located at Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India.

ANSWER: Denied.

6. On information and belief, Hetero Labs Ltd. is a parent company of Hetero USA Inc.

ANSWER: Admitted.

7. On information and belief, Hetero Labs Ltd., Hetero Labs Ltd. Unit-VI, and Hetero USA Inc. are related entities and each entity undertakes certain activities related to the development, manufacture, marketing, and/or sale of drug products in the United States and in this Judicial District.

ANSWER: Denied.

8. Upon information and belief, Defendants derive substantial revenue from the sale of generic pharmaceutical products in the United States and Delaware.

ANSWER: Denied.

JURISDICTION AND VENUE

9. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 1 *et seq.*, and alleges infringement of the ’952 Patent.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that Plaintiff’s Complaint purports to assert an action for patent infringement under the patent laws of the United States, including 35 U.S.C. § 1 *et seq.*, and alleges infringement of the ’952 Patent. Hetero denies any remaining allegations contained in Paragraph 9 of the Complaint.

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has subject matter jurisdiction over this action. Hetero denies any remaining allegations contained in Paragraph 10 of the Complaint.

11. This Court has personal jurisdiction over Hetero USA Inc. On information and belief, Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Hetero USA Inc. maintains an agent for service of process at 3500 S Dupont Highway, Dover DE 19901.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero USA Inc. Hetero denies any remaining allegations contained in Paragraph 11 of the Complaint.

12. This Court has personal jurisdiction over Hetero USA Inc. at least because, upon information and belief, Hetero USA Inc. has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Hetero USA Inc. directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Hetero USA Inc. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or

things used or consumed in Delaware, thereby demonstrating that Hetero USA Inc. has continuous and systematic contacts with Delaware.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero USA Inc. Hetero denies any remaining allegations contained in Paragraph 12 of the Complaint.

13. Hetero USA Inc. regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g, , Novartis Pharmaceuticals Corp. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 19-2053-LPS (D. Del. Jan. 27, 2020), D.I. 30; *Genentech, Inc. et al. v. Hetero Labs Ltd. et al.*, C.A. No. 19-178-RGA (D. Del. Apr. 1, 2019), D.I. 11; *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, C.A. No. 17- 825-MN (D. Del. Oct. 16, 2017), D.I. 13; *Sanofi-Aventis U.S. LLC, et al. v. Actavis LLC, et al.*, C.A. No. 20-804-RGA (D. Del. July 20, 2020), D.I. 36; *Bristol-Myers Squibb Co. et al. v. Hetero USA Inc. et al.*, C.A. No. 17-376-LPS (D. Del. Jun. 16, 2017), D.I. 9; and *Amgen Inc. v. Hetero USA Inc. et al.*, C.A. No. 16-928-GMS (D. Del. Dec. 2, 2016), D.I. 12.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero USA Inc. Hetero denies any remaining allegations contained in Paragraph 13 of the Complaint.

14. This Court has personal jurisdiction over Hetero Labs Ltd. at least because, upon information and belief, Hetero Labs Ltd. has purposefully availed itself of the benefits and

protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Hetero Labs Ltd. directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Hetero Labs Ltd. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, thereby demonstrating that Hetero Labs Ltd. has continuous and systematic contacts with Delaware.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero Labs Ltd. Hetero denies any remaining allegations contained in Paragraph 14 of the Complaint.

15. Hetero Labs Ltd. regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g,* [sic] *Novartis Pharmaceuticals Corp. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 19-2053-LPS (D. Del. Jan. 27, 2020), D.I. 30; *Genentech, Inc. et al. v. Hetero Labs Ltd. et al.*, C.A. No. 19-178-RGA (D. Del. Apr. 1, 2019), D.I. 11; *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, C.A. No. 17- 825-MN (D. Del. Oct. 16, 2017), D.I. 13; *Sanofi-Aventis U.S. LLC, et al. v. Actavis LLC, et al.*, C.A. No. 20-804-RGA (D. Del. July 20, 2020), D.I. 36; *Bristol-Myers Squibb Co. et al. v. Hetero USA Inc. et al.*, C.A. No. 17-376-LPS (D. Del. Jun. 16, 2017), D.I. 9; and *Amgen Inc. v. Hetero USA Inc. et al.*, C.A. No. 16-928-GMS (D. Del. Dec. 2, 2016), D.I. 12.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero Labs Ltd. Hetero denies any remaining allegations contained in Paragraph 15 of the Complaint.

16. Hetero Labs Ltd. is also subject to personal jurisdiction in the State of Delaware because Hetero Labs Ltd. has committed, aided, abetted, contributed to, and/or participated in the commission of tortious acts of patent infringement under 35 U.S.C. § 271(e)(2) that have led and/or will lead to foreseeable harm and injury to Plaintiff Ingenus Pharmaceuticals LLC.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero Labs Ltd. Hetero denies any remaining allegations contained in Paragraph 16 of the Complaint.

17. This Court has personal jurisdiction over Hetero Labs Ltd. Unit-VI, at least because, upon information and belief, Hetero Labs Ltd. Unit-VI has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Hetero Labs Ltd. Unit-VI directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Hetero Labs Ltd. Unit-VI regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, thereby demonstrating that Hetero Labs Ltd. Unit-VI has continuous and systematic contacts with Delaware.

ANSWER: Denied.

18. Hetero Labs Ltd. Unit-VI regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Novartis Pharmaceuticals Corp. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 19-2053-LPS (D. Del. Jan. 27, 2020), D.I. 30; *Genentech, Inc. et al. v. Hetero Labs Ltd. et al.*, C.A. No. 19-178-RGA (D. Del. Apr. 1, 2019), D.I. 11; *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, C.A. No. 17- 825-MN (D. Del. Oct. 16, 2017), D.I. 13; *Sanofi-Aventis U.S. LLC, et al. v. Actavis LLC, et al.*, C.A. No. 20-804-RGA (D. Del. July 20, 2020), D.I. 36; *Bristol-Myers Squibb Co. et al. v. Hetero USA Inc. et al.*, C.A. No. 17-376-LPS (D. Del. Jun. 16, 2017), D.I. 9; and *Amgen Inc. v. Hetero USA Inc. et al.*, C.A. No. 16-928-GMS (D. Del. Dec. 2, 2016), D.I. 12.

ANSWER: Denied.

19. Hetero Labs Ltd. Unit-VI is also subject to personal jurisdiction in the State of Delaware because Hetero Labs Ltd. Unit-VI has committed, aided, abetted, contributed to, and/or participated in the commission of tortious acts of patent infringement under 35 U.S.C. § 271(e)(2) that have led and/or will lead to foreseeable harm and injury to Plaintiff Ingenus Pharmaceuticals LLC.

ANSWER: Denied.

20. This Court has personal jurisdiction over Hetero at least because, upon information and belief, Hetero is the current owner of Abbreviated New Drug Application (ANDA) No. 219271 ("Hetero's ANDA") and is seeking final approval of that ANDA to engage in the commercial use, sale, and/or distribution of cyclophosphamide solution for intravenous injection, 500 mg/2.5 mL (200 mg/mL), 1 gm/5 mL (200 mg/mL), and 2 gm/10 mL (200 mg/mL) ("Hetero's

ANDA Product" or "ANDA Product"), throughout the United States, including in Delaware, before the expiration of the '952 Patent.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero USA Inc. and Hetero Labs Ltd. Hetero denies any remaining allegations contained in Paragraph 20 of the Complaint.

21. This Court has personal jurisdiction over Hetero at least because, upon information and belief, if Hetero's ANDA receives final approval, Hetero's ANDA Product will be manufactured, sold, distributed, and/or used by Hetero in Delaware; prescribed by physicians practicing in Delaware; and/or administered to patients in Delaware.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has personal jurisdiction over Hetero USA Inc. and Hetero Labs Ltd. Hetero denies any remaining allegations contained in Paragraph 21 of the Complaint.

22. Hetero committed an act of infringement of the '952 Patent by submitting and maintaining ANDA No. 219271 with the intent to make, use, offer to sell, and/or sell the drug products that are the subject of ANDA No. 219271 in this Judicial District, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Plaintiff, which manufactures Cyclophosphamide Injection for sale and use throughout the United States, including within this judicial district. On information and belief and as indicated by a letter dated July 31, 2024, sent by Hetero USA, Inc. and addressed to Ingenus Pharmaceuticals LLC, Leiutis Pharmaceuticals LLP and Dr. Reddy's laboratories, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (hereinafter, the "Notice

Letter"), ANDA No. 219271 was prepared and filed with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

ANSWER: Denied.

23. On information and belief, Hetero plans to sell its ANDA Product in the State of Delaware, list the ANDA Product on the State of Delaware' prescription drug formulary, and seek Medicaid reimbursements for sales of the ANDA Product in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Denied.

24. On information and belief, Hetero intends that its proposed ANDA Product will be distributed and sold in Delaware and will thereby displace sales of Plaintiff's Cyclophosphamide Injection, causing injury to Ingenus. Hetero intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed ANDA Product.

ANSWER: Denied.

25. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest the propriety of venue in this District. Hetero denies all remaining allegations of Paragraph 25.

PLAINTIFF'S APPROVED DRUG PRODUCT AND U.S. PATENT No. 10,993,952

26. By License Agreement of June 11, 2024, Dr. Reddy's Laboratories, Inc. ("DRL") has become Ingenus' Licensee of New Drug Application (NDA) No. 212501, which was approved by the Food and Drug Administration ("FDA") for the sale and manufacture of Cyclophosphamide

solution for intravenous use ("NDA Product"). The active ingredient in the Cyclophosphamide NDA Product is cyclophosphamide. The FDA approved NDA No. 212501 on July 30, 2020.

ANSWER: Hetero admits that NDA No. 212501 was approved by the Food and Drug Administration ("FDA") for the sale and manufacture of Cyclophosphamide solution. Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 26 of the Complaint and, therefore, denies them.

27. Under the terms of the License Agreement, Ingenus manufactures and supplies to DRL the Products approved under NDA 212501 and DRL markets and commercializes the same, subject to the terms of the License Agreement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 27 of the Complaint and, therefore, denies all allegations.

28. NDA No. 212501 is directed to Cyclophosphamide 200 mg/mL (500 mg/ 2.5 mL and 1 g/ 5 mL) in a multiple-dose vial. A supplemental dosage form 200 mg/mL (2 g/ 10 ml) was approved November 19, 2021, under New Drug Application No. N212501.

ANSWER: Hetero admits that NDA No. 212501 is directed to Cyclophosphamide 200 mg/mL (500 mg/ 2.5 mL and 1 g/ 5 mL). Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 28 of the Complaint and, therefore, denies them.

29. Plaintiff's Cyclophosphamide NDA Product is an injectable solution indicated for the treatment of malignant diseases such as malignant lymphomas (Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma); multiple myeloma, leukemias (chronic lymphocytic leukemia, chronic granulocytic leukemia,

acute myelogenous and monocytic leukemia, acute lymphoblastic (stem-cell) leukemia); mycosis fungoides, neuroblastoma, adenocarcinoma of the ovary, retinoblastoma, and breast carcinoma.

ANSWER: Hetero admits that the prescribing information for Plaintiff's Cyclophosphamide product speaks for itself. Hetero denies the remaining allegations of Paragraph 29 of the Complaint.

30. Plaintiff's Cyclophosphamide NDA Product's recommended dosage is 40 mg per kg to 50 mg per kg in divided doses over 2 to 5 days.

ANSWER: Hetero admits that the prescribing information for Plaintiff's Cyclophosphamide product speaks for itself. Hetero denies the remaining allegations of Paragraph 30 of the Complaint.

31. The '952 Patent, entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations," was duly and legally issued by the U.S. Patent and Trademark Office on May 4, 2021.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '952 patent is entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations." Hetero denies that the '952 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph31.

32. Ingenus is the sole owner and assignee of the '952 Patent, based on an Assignment of all right, title and interest by Assignor Leiutis Pharmaceuticals LLP of July 4, 2024, recorded at the U.S. Patent and Trademark Office on July 10, 2024 at Reel/Frame No. 067935/0049. Prior to the Assignment by Leiutis, Ingenus and Leiutis were co-assignees of the '952 Patent.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero is without sufficient information with which to form a

belief as to the truth or accuracy of the allegations in Paragraph 32 of the Complaint and, therefore, denies all allegations.

33. Pursuant to 21 U.S.C. § 355(b)(1), the '952 Patent was submitted to FDA with NDA No. 212501 and was subsequently listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for Cyclophosphamide Injection.

ANSWER: Upon information and belief, Hetero admits that FDA's Orange Book lists the '952 patent in connection with NDA No. 212501. Hetero lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 33 and, therefore, denies those allegations.

DEFENDANTS' ANDA NO. 219271

34. On information and belief, Defendants have submitted ANDA No. 219271 to FDA, or caused ANDA No. 219271 to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of cyclophosphamide injection as purported generic versions of Plaintiff's NDA Products prior to the expiration of the '952 Patent.

ANSWER: Hetero admits that it submitted ANDA No. 219721 seeking approval to market Hetero's Proposed ANDA Product. Hetero denies all remaining allegations of Paragraph 34 of the Complaint.

35. On information and belief, Hetero USA Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI acted collaboratively in the preparation and submission of ANDA No. 219271 and Hetero's Proposed ANDA Product, and all intend to directly benefit from and have a financial stake in the approval of the ANDA.

ANSWER: Denied.

36. On information and belief, following any FDA approval of ANDA No. 219271, Hetero USA Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI will work in concert with one another to make, use, offer to sell, and/or sell the drug product that is the subject of ANDA No. 219271 throughout the United States, and/or import such drug product into the United States, including in this Judicial District.

ANSWER: Denied.

37. On information and belief, FDA has not approved Defendants' ANDA.

ANSWER: Admitted.

38. By letter dated July 31, 2024, Hetero USA, Inc. notified Ingenus Pharmaceuticals LLC, Leiutis Pharmaceuticals LLP and Dr. Reddy's Laboratories, Inc. that Hetero submitted to FDA ANDA No. 219271 containing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '952 Patent, which is listed in the Orange Book for Plaintiff's NDA Products, asserting that the'952 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Hetero's Proposed ANDA Product. Plaintiff reserves all rights to challenge the sufficiency of Defendants' ANDA and Notice Letter.

ANSWER: Hetero admits that it sent written notice of a Paragraph IV Certification ("Hetero's Notice Letter") to Plaintiffs on or around July 31, 2024. Hetero's Notice Letter speaks for itself. Hetero denies all remaining allegations of Paragraph 38 of the Complaint.

39. On information and belief, Defendants seek approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Product before expiration of the '952 Patent. Hence, Defendants' purpose in submitting ANDA No. 219271 with a Paragraph

IV certification is to market the ANDA product described therein before the expiration of the '952 Patent.

ANSWER: Hetero's Notice Letter speaks for itself. Hetero denies all remaining allegations of Paragraph 39 of the Complaint.

40. On information and belief, if approved, the ANDA Product will have the same indication as Plaintiff's Cyclophosphamide NDA Product. On further information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 219271 for the ANDA Product is the treatment of malignant diseases as described in Plaintiff's NDA.

ANSWER: Hetero's proposed labeling speaks for itself. Hetero denies all remaining allegations in Paragraph 40 of the Complaint.

41. On information and belief, if FDA approves Defendants' ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Product, within the United States, including within the State of Delaware, or will import the ANDA Product into the United States, including into the State of Delaware.

ANSWER: Denied.

42. On information and belief, if FDA approves Defendants' ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product in a manner that infringes the '952 Patent.

ANSWER: Denied.

43. This action is being brought within forty-five days of Plaintiff's receipt of the Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). Accordingly, Plaintiff is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that this action is being brought within 45 days of Hetero's Notice Letter. Hetero denies all remaining allegations of Paragraph 43 of the Complaint.

FIRST COUNT
(Hetero's Infringement of the '952 Patent)

44. Plaintiff repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

45. Upon information and belief, Hetero submitted or caused the submission of ANDA No. 219271 to FDA, seeking FDA approval of Defendants' ANDA.

ANSWER: Admitted.

46. Plaintiff owns substantial rights, title, and interest in and to the '952 Patent.

ANSWER: Denied.

47. Hetero's ANDA Product falls within one or more claims of the '952 Patent.

ANSWER: Denied.

48. Hetero does not contest infringement of any claims of the '952 Patent in its Notice Letter. If Hetero had a factual or legal basis to contest infringement of any claims of the '952 Patent, Hetero was required by applicable regulations to state such a basis in its Notice Letter. See 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

ANSWER: Denied.

49. Under 35 U.S.C. § 271(e)(2)(A), Hetero's submission of Hetero's ANDA with a Paragraph IV certification to the '952 Patent for the purpose of obtaining approval to engage in

the commercial manufacture, use, or sale of Hetero's ANDA Product before the expiration of the '952 Patent is itself an act of infringement of the '952 Patent.

ANSWER: Denied.

50. If approved by the FDA, the importation, manufacture, sale, offer for sale, or use of the ANDA Product within the United States will infringe, either literally or under the doctrine of equivalents, one or more claims of the '952 Patent under 35 U.S.C. § 271(a).

ANSWER: Denied.

51. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '952 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendants' ANDA, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby induce infringement of one or more claims of the '952 Patent. On information and belief, upon FDA approval, Defendants will intentionally encourage acts of direct infringement with knowledge of the '952 Patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

52. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the '952 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants' ANDA, Defendant will offer to sell or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of one or more claims of the '952 Patent. On information and belief, Defendants have had and continues to have knowledge of the '952 Patent and knowledge that its acts will lead to infringement of the patent. On information and belief, Defendants have had and continue to have

knowledge that the ANDA Product is especially made or especially adapted for a use that infringes the ’952 Patent and that there are no substantial noninfringing uses for the ANDA Product.

ANSWER: Denied.

53. Defendants had actual and constructive notice of the ’952 Patent prior to filing Defendants’ ANDA, and was aware that the filing of Defendants’ ANDA with the request for FDA approval prior to the expiration of the ’952 Patent would constitute an act of infringement of the ’952 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not infringe, contribute to the infringement of, and/or induce the infringement of the ’952 Patent.

ANSWER: Denied.

54. Defendants filed their ANDA without adequate justification for asserting the ’952 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants’ conduct in certifying invalidity, unenforceability, and/or noninfringement with respect to the ’952 Patent was willful and renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285 and entitles Plaintiff to recovery of their attorneys’ fees and such other relief as this Court deems proper.

ANSWER: Denied.

55. Plaintiff will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the ’952 Patent. Plaintiff does not have an adequate remedy at law and considering the balance of hardships between Plaintiff and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

GENERAL DENIAL AND RESPONSE TO PRAYER FOR RELIEF

To the extent not specifically admitted above, Hetero hereby denies all allegations in the Complaint. Hetero further denies that Plaintiff is entitled to any relief whatsoever. Hetero denies that Plaintiff is entitled to the judgment or other relief prayed for in Paragraphs A-J of the Complaint under the heading PRAYER FOR RELIEF.

HETERO'S DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Hetero avers and asserts the following separate defenses to the Complaint:

FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '952 PATENT)

The claims of the '952 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '952 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219271 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '952 Patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '952 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219271 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '952 Patent.

FOURTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiff's Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

FIFTH SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

Plaintiff's Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and/or (c).

SIXTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM FOR EXCEPTIONAL OR WILLFUL INFRINGEMENT)

Plaintiff fails to state a proper claim for an exceptional case and/or willful infringement.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to injunctive relief against Hetero because Plaintiff's alleged damages are not immediate or irreparable, and therefore Plaintiff has an adequate remedy at law. Moreover, considering the balance of hardships between the parties, and the public interest in fostering the prompt introduction of generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to attorney's fees against Hetero because Plaintiff has not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285.

NINTH AFFIRMATIVE DEFENSE

35 U.S.C. § 288 prevents Plaintiff from recovering any costs associated with this action.

TENTH AFFIRMATIVE DEFENSE

Plaintiff's allegations are barred, in whole or in part, by the doctrines of waiver, estoppel and/or prosecution history estoppel.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's allegations are barred by the doctrine of collateral estoppel based on the judgment in *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case No. 22-02868.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Hetero reserves the right to plead additional separate defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

HETERO'S COUNTERCLAIMS

For its counterclaims against Counterclaim-Defendant Ingenus Pharmaceuticals, LLC ("Ingenus" or "Counterclaim-Defendant"), Counterclaim-Plaintiff Hetero USA, Inc., Hetero Labs Ltd. Unit-V, and Hetero Labs Ltd. (collectively, "Hetero" or "Counterclaim-Plaintiffs"), state as follows:

PARTIES

1. On information and belief, Ingenus is a corporation organized and existing under the laws of the state of Florida having its principal place of business at 4190 Millenia Blvd., Orlando, Florida 32839.

2. Counterclaim-Plaintiff Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at Floor 9-11, Tower 30, RMZ Nexity Sy. No. 83/1, Knowledge City, Raidurg, Hyderabad – 500081, Telangana, India.

3. Counterclaim-Plaintiff Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

NATURE OF THE ACTION

4. Hetero seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that United States Patent No. 10,993,952 ("the '952 patent" or the "Patent-In-Suit") is invalid and/or not infringed.

JURISDICTION AND VENUE

5. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Ingenus because, among other reasons, Ingenus subjected itself to the jurisdiction of this Court by filing its complaint here.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Plaintiff's choice of forum.

8. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the Patent-in-Suit.

BACKGROUND

A. FDA Approval of New Brand Name Drugs

9. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

10. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

11. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

12. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

13. FDA's duties with respect to the Orange Book are purely ministerial. If the NDA holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval of New Generic Drugs

14. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

15. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the

FDA what is called an Abbreviated New Drug Application ("ANDA").

16. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

17. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

18. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of each of its paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

19. Upon receiving notice of the paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

20. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the paragraph IV certifications because doing so, regardless of merit, prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions requiring court actions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

21. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the proposed product in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, the FDA may approve the ANDA effective on the date when the court enters the

judgment. *Id.*

C. Hetero's ANDA and Plaintiff' Complaint

22. Hetero submitted Abbreviated New Drug Application ("ANDA") No. 219271 ("Hetero's ANDA") to obtain FDA approval to engage in the commercial manufacture, use, and sale of generic Cyclophosphamide Solution ("Hetero's ANDA Product").

23. On information and belief, Ingenus holds approved New Drug Application ("NDA") No. 212501 for Cyclophosphamide Solution under Section 505(b) of the Federal Food Drug and Cosmetic Act ("FFDCA").

24. Hetero's ANDA shows that Hetero's ANDA Products are bioequivalent to the products that are the subject of NDA No. 212501.

25. On information and belief, Ingenus caused the '952 patent to be listed in the publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly called the "Orange Book," as a patent that purportedly claims the drug listed in, and/or purportedly claim a method of using the drug for which Ingenus submitted, NDA No. 212501.

26. The '952 patent is entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations" and the issue date identified on the cover of the '952 patent is May 4, 2021.

27. Hetero's ANDA contains "Paragraph IV" certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '952 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Hetero's ANDA Product.

28. On July 31, 2024, Hetero sent Plaintiff written notice of Hetero's Paragraph IV Certifications ("Hetero's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Hetero's Notice Letter asserted that the claims of the '952 patent are invalid, unenforceable, and/or will not be infringed by Hetero's ANDA or the products or activities described therein.

29. Hetero's Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV certifications included in Hetero's ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

30. On September 11, 2024, Plaintiff filed the present lawsuit alleging infringement of the '952 patent. There has been and now is an actual and justiciable controversy between Hetero and Plaintiff as to whether Hetero's ANDA Product infringes, induces infringement, or contributes to the infringement of any valid and enforceable claim of the '952 patent.

COUNT I
Declaratory Judgment of Non-Infringement of the '952 Patent

31. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

32. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '952 patent.

33. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '952 patent is not infringed by Hetero's ANDA or the products or activities described therein.

34. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '952 patent and is not liable for such infringement.

COUNT II
Declaratory Judgment of Invalidity of the '952 Patent

35. Hetero incorporates by reference the allegations in the foregoing paragraphs of its

counterclaims.

36. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the '952 patent are invalid.

37. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '952 patent are invalid.

38. Hetero is entitled to a declaration that all claims of the '952 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

HETERO'S REQUEST FOR RELIEF

WHEREFORE, Hetero respectfully requests that this Court enter a judgment in its favor and against Plaintiff as follows:

(a) Dismissing the Complaint with prejudice and entering judgment for Hetero;

(b) Declaring that no valid claim of the Patent-in-Suit would be infringed by the manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Products pursuant to ANDA No. 219271

(c) Declaring that the claims of the Patent-in-Suit are invalid;

(d) Entering judgment for Hetero on its affirmative defenses and any and all additional defenses and counterclaims that discovery may reveal;

(e) Enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Counterclaim-Defendant from threatening to assert or otherwise attempting to enforce the Patent-in-Suit against Hetero, its customers, suppliers, or anyone in privity with Hetero;

(f) Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Hetero its reasonable attorneys' fees and costs incurred in this action;

(g) Awarding Hetero its costs and expenses incurred in this action; and

(h) Awarding Hetero such other and further relief as this Court may deem proper.

Dated: ~~October 3, 2024~~June ___, 2025

/s/ Kenneth L. Dorsney

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